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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,268	09/29/2003	Michael Fantuzzi	33503/US	3101

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Scott D. Rothenberger  
DORSEY & WHITNEY LLP  
Intellectual Property Department  
50 South Sixth Street, Suite 1500  
Minneapolis, MN 55402-1498

EXAMINER

KOSSON, ROSANNE

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/674,268

Applicant(s)

FANTUZZI, MICHAEL

Examiner

Rosanne Kosson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,18-20,22,23,25-34 and 36-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-15, 18-20, 22, 23, 25-34, 36-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/15/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 15, 2005 has been entered.

No claims have been amended, added or canceled. Accordingly, claims 1, 2, 5-15, 18-20, 22, 23, 25-34, 36-51 are examined on the merits herewith.

### ***Claim Rejections - 35 USC § 102***

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 8-10, 13, 26-28 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Erwin (US 2005/0025756). Erwin discloses and claims (see claim 3) a composition comprising coenzyme Q-10 (coQ 10) dissolved in d-limonene and a carrier (see paragraphs 6, 37, 40, 41, 53, 54 and 61). The composition may also comprise an antioxidant, such as vitamin E (see paragraphs 8, 43, 48, 55 and 58). In addition to other carriers which may be present in the chemical combinations of Erwin,

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D-limonene is a carrier and an oil. Vitamin E,  $\alpha$ -tocopherol, is an oil. Therefore, a holding of anticipation is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 11, 12, 14, 15, 18-20, 22, 23, 25, 29, 30, 32-34, 36-42, are 43-51 rejected under 35 U.S.C. 103(a) as being unpatentable over Erwin (US 2005/0025756) in view of Soft Gel Technologies, Inc. (EP 888774) and Davidson et al. (US 2004/0001874). The teachings of Erwin are discussed above. Soft Gel discloses that coenzyme Q-10 (coQ 10) may be dissolved in rice bran oil, a plant oil, and formulated into soft gel capsules. Vitamin E, another oil, may be mixed with the rice bran oil before it is encapsulated so that soft gel capsules containing 30 mg of coQ 10 and 30 IU of vitamin E are produced (see p. 2, lines 5-7 and 51-52; and p. 3, lines 4-5). When coQ 10 is dissolved in a plant oil, the bioavailability is improved over a dry formulation, as shown by increased blood levels of coQ 10 in subjects receiving the soft gel capsules (see p. 3, lines 12-13; p. 3, line 54, to p. 4, line 16; and Tables I and II). It would have been obvious to one of ordinary skill in the art at the time that the invention was made to formulate the composition of Erwin as a soft gel capsule in which coQ 10 is dissolved in a plant oil, because Soft Gel teaches that these capsules are easily administered to

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humans and that when coQ 10 is dissolved in a plant oil, more of it absorbed into the bloodstream, compared to dry capsules. Erwin teaches that the plant oil may be d-limonene. As noted above, Erwin also teaches adding a second anti-oxidant, vitamin E, to the composition containing coQ 10 to improve the health benefits of the composition.

Davidson et al. disclose soft gel capsules containing fish oil into which coQ 10 is blended. Fish oil reduces serum triglyceride levels and reduces the incidence of death from cardiovascular disease. Patients with cardiovascular disease often take statin drugs, which deplete the body's coQ 10, thereby causing muscle toxicity (myopathy) (see paragraphs 55 and 57). The soft gel capsules of Davidson et al. replenish the coQ 10 in the body and also treat hypertriglyceridemia. It would have been obvious to one of ordinary skill in the art to formulate the composition of Erwin as a soft gel fish oil capsule in which the coQ 10, dissolved in limonene, is blended into the fish oil, because Davidson et al. teach that these capsules can both treat high triglyceride levels and provide coQ 10 to humans.

Regarding claims 25, 32 and 42, none of the cited references discloses dissolving coQ 10 in an amount of about 30-45% by weight in limonene. Erwin discloses dissolving an amount of about 15%, for illustrative purposes only (see paragraph 47), and an amount of at least 1%. But dissolving 30 or 45% versus 15% does not appear to be associated with any particular result or effect. It would have been obvious to one of ordinary skill in the art that, compared to one particular oil composition containing coQ 10, if two or three times as much were dissolved, the more concentrated oils would deliver more coQ 10 to a subject. A more concentrated oil might provide

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higher blood levels of coQ 10 and somewhat more benefit (more protection from oxidative damage, more energy, improved muscle functioning), but that would be an expected result.

In view of the foregoing, a holding of obviousness is required.

No claim is allowed.

***Declaration under 37 CFR 1.131***

The Declaration filed on September 15, 2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the reference cited therein. Applicant has filed this Declaration and an Information Disclosure Statement for the purpose of antedating the disclosure of Erwin (US 2005/0025756), which claims priority to Provisional Application No. 60/482,781, filed on June 25, 2003.

This reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

See also 37 CFR §1.131 and MPEP 706.02(a)(II)(B) and 706.02(f)(1)(II) Example 2. The MPEP sections discuss the effective filing date of a §102(e) reference.

Further, the Declaration was submitted without supporting evidence and explanations that are direct links between statements in the Declaration and facts shown in the supporting documentation.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner, Art Unit 1653

rk/2005-09-23



ROBERT A. WAX  
PRIMARY EXAMINER